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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/880,708	06/12/2001	Se-Jin Lee	JHU1320-4	7387

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EXAMINER	
ROMEO, DAVID S	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 06/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/880,708	LEE ET AL.	
	Examiner	Art Unit	
	David S. Romeo	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2 and 5-14* is/are pending in the application.

4a) Of the above claim(s) *9,10,13 and 14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,5-8,11 and 12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *2 and 5-14* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

5.00

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/14/2005 has been entered.

Claims 2, 5-14 are pending. Claims 9, 10, 13, 14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the paper filed 11/07/2002 (Paper No. 9). Claims 2, 5-8, 11, 12 are being examined.

Applicant's arguments with respect to claims 2, 5-8, 11, 12 have been considered but are moot in view of the new ground(s) of rejection.

New Formal Matters, Objections, and/or Rejections:

Claim Rejections - 35 USC § 112

Claims 2, 5-8, 11, 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2, 5-8, 11, 12 are indefinite over the recitation of "control group specimen." The term "control group specimen" in claim 2 is relative to "uterine neoplasm tissue or endometriosis tissue or skeletal tissue." However, the specification does not define the term. The specification does not provide some standard for determining a control group specification. The specification does not describe any specimens in such a group nor does it describe the GDF-5 levels in such specimens. Thus, it is unclear what "control group specimen" Applicants intend. The metes and bounds are not clearly set forth.

Applicants argue that the terms "control" and "control group," as used in the biological and chemical arts, confer the listed general meanings. Applicant's arguments have been fully considered but they are not persuasive. The specification does not define the term. Extrinsic evidence may not be used to vary, contradict, expand, or limit the claim language from how it is defined, even by implication, in the specification. In addition, this extrinsic evidence would not provide notice to the public as to the metes and bounds of patentee's rights when the patent issues. In light of the specification one of ordinary skill in the art would not understand what is claimed. Furthermore, the term "the specimen" in line 9 of claim 2, has an antecedent basis in "tissue specimen of the subject" and "control group specimen," which leads to further uncertainty as how to construe "tissue specimen of the subject" and "control group specimen."

Claims 2, 5-8, 11, 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2, and hence claims 5-8, 11, 12, recite the term "the specimen" in line 9. The antecedent basis for this term is unclear. It is unclear if the term refers to "a tissue specimen" or "a control group specimen." The metes and bounds are not clearly set forth.

Claims 2, 5-8, 11, 12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Support for the presently claimed invention cannot be found in the disclosure as originally filed, particularly with respect to "tissue of a specimen subject," "control group specimen," and "endometrial tissue," which raises the issue of new matter. The examiner has consider all the passages of the specification that Applicants regard as fully supporting and enabling claim 2, as indicated at page 6, full paragraph 1, of Applicants' response filed 03/14/2005. However, these passages do not support the literal language of the claims.

The specification contains the following passage relevant to "endometriosis":

> The expression of GDF-5 in the uterus suggests a variety of applications using the polypeptide, polynucleotide, and antibodies of the invention, related to contraception, fertility, pregnancy, and cell proliferative diseases. Abnormally low levels of the factor may be indicative of impaired function in the uterus while abnormally high levels may be indicative of hypertrophy, hyperplasia, or the presence of ectopic tissue. Hence, GDF-5 may be useful in detecting not only primary and metastatic neoplasms of uterine origin but in detecting diseases such as endometriosis as well. In addition, GDF-5 may also be useful as an indicator of developmental anomalies in prenatal screening procedures. Page 6, full paragraph 3.

The specification contains the following passage relevant to "detecting binding of the antibody" and "specimen":

> The invention provides a method for detecting a cell proliferative disorder of the uterus or skeletal system (e.g., bone, cartilage) which comprises contacting an anti-GDF-5 antibody with a cell suspected of having a GDF-5 associated disorder and detecting binding to the antibody. The antibody reactive with GDF-5 is labeled with a compound which allows detection of binding to GDF-5. For purposes of the invention, an antibody specific for GDF-5 polypeptide may be used to detect the level of GDF-5 in biological fluids and tissues. Any specimen containing a detectable amount of antigen can be used. A preferred sample of this invention is tissue of uterine origin, specifically endometrial tissue or skeletal tissue such as bone and cartilage. The level of GDF-5 in the suspect cell can be compared with the level in a normal cell to determine whether the subject has a GDF-5-associated cell proliferative disorder. Preferably the subject is human. Page 15, full paragraph 1.

The specification contains the following passage relevant to *in vivo* diagnosis:

> In using the monoclonal antibodies of the invention for the in vivo detection of antigen, the detectably labeled antibody is given a dose which is diagnostically effective. The term "diagnostically effective" means that the amount of detectably labeled monoclonal antibody is administered in sufficient quantity to enable detection of the site having the antigen comprising a polypeptide of the invention for which the monoclonal antibodies are specific. Paragraph bridging pages 16-17.

The specification contains the following passage relevant to measuring increases or decreases in GDF-5:

> The monoclonal antibodies of the invention can be used in vitro and in vivo to monitor the course of amelioration of a GDF-5-associated disease in a subject. Thus, for example, by measuring the increase or decrease in the number of cells expressing antigen comprising a polypeptide of the invention or changes in the concentration of such antigen present in various body fluids and tissues, it would be possible to determine whether a particular therapeutic regimen aimed at ameliorating the GDF-5-associated disease is effective. The term "ameliorate" denotes a lessening of the detrimental effect of the GDF-5-associated disease in the subject receiving therapy. Page 18, full paragraph 2.

The specification contains the following passage relevant to "altered expression" GDF-5:

> The present invention identifies a nucleotide sequence that can be expressed in an altered manner as compared to expression in a normal cell, therefore it is possible to design appropriate therapeutic or diagnostic techniques directed to this sequence. Thus, where a cell-proliferative disorder is associated with the expression of GDF-5, nucleic acid sequences that interfere with GDF-5 expression at the translational level can be used. This approach utilizes, for example, antisense nucleic acid and ribozymes to block translation of a specific GDF-5 DNA, either by masking that mRNA with an antisense nucleic acid or by cleaving it with a ribozyme. Page 18, full paragraph 3.

These passages do not implicitly support the literal language of the claims because endometriosis is a condition it is not a tissue; and because the specification only teaches comparing the GDF-5 level to the "level in a normal cell to determine whether the subject has a GDF-5-associated cell proliferative disorder," not to "a control group specimen."

Conclusion

No claims are allowable.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Neidhardt (AC, cited by Applicants) discloses antibodies capable of binding MP52 (paragraph bridging pages 9-10).

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (571) 272-0890. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M. IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, BRENDA BRUMBACK, CAN BE REACHED ON (571) 272-0961.

IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE CENTRAL FAX NUMBER FOR OFFICIAL CORRESPONDENCE, WHICH IS (571) 273-8300.

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (571) 273-0890.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

David Romeo

DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

DSR
MAY 27, 2005